

REMARKS

This Amendment is in response to the non-final Office Action in which pending claims 17-27 stand rejected.

Upon entry of this Amendment, dependent claim 19 is amended, no claims are canceled, and no new claims are added.

Entry and favorable consideration of this Amendment is earnestly solicited, which is intended to place the application in condition for allowance without introducing new issues requiring additional search or consideration by the Examiner.

The following remarks are respectfully submitted.

I. Rejections under 35 USC §112

Claim 22 stands rejected as allegedly as not complying with the written description requirement (paragraph 1) regarding triple chamber cardiac resynchronization therapy.

Applicants respectfully traverse the rejection.

Support for triple chamber resynchronization is expressly included in the application as filed; that is, at page 11, lines 20 to 23 the following makes clear to one of skill in the art that the limitation is supported.

Ventricular timing during **atrial-synchronized bi-ventricular pacing (cardiac resynchronization therapy) may be performed** at about the same time as the SCS to further improve the performance and efficiency of the heart. (emphasis added.)

In addition, at page 12, lines 1-4 the subject matter is again referenced with enough detail to place that aspect of the invention in context; to wit:

Additionally, **the stimulation therapy may be administered along with cardiac resynchronization therapy** to further improve the cardiac performance and efficiency of the heart. That is, the SCS or another stimulation (e.g. TENs, subcutaneous) therapy may be administer shortly before, shortly after, or at the same time as resynchronization or other pacing therapy. (emphasis added.)

Accordingly, the rejection stands traversed and should be withdrawn.

II. Rejections under 35 USC §103

Claims 17, 18, and 20-27 stand rejected under 35 USC §103(a) as allegedly being unpatentable over the '428 patent to Obel et al. (Obel) and the '326 patent to Collins (Collins) in view of the '898 patent to Limousin (Limousin).

The claims are directed to methods and apparatus which treats a patient to improve cardiac performance and efficiency of the patient's heart through the use of both direct electrical nerve stimulation to improve balance of a neuro-endocrinological system and the delivery of a cardiac resynchronization pacing therapy to the patient's heart to improve cardiac output.

As noted previously, the notion of delivering CRT to improve cardiac performance (e.g., hemodynamics) and efficiency (e.g., balance between supply and demand and balance within the neuro-endocrinological systems) of a patient's heart is not taught or suggested by Obel or Collins.

Obel is directed to use of vagal stimulation to treat conditions of ischemia. Obel suggests the use of backup brady and tachycardia pacing therapies. (Obel, col. 6, line 66-col. 7, line 2). Obel does not suggest a combined use of electrical nerve stimulation and CRT pacing therapy that increase cardiac output to achieve improved cardiac performance and efficiency.

Collins discloses an antiarrhythmia pacemaker that delivers antiarrhythmia therapy using both electrical stimulation of the heart and electrical stimulation of the autonomic nervous system. Collins does not, however, teach the use of nerve stimulation and CRT pacing therapies, which together achieve improved cardiac performance and efficiency. The objective of the particular pacing and nerve stimulation delivered in Collins is to detect and treat arrhythmias in a patient's heart.

Limousin fails to even contemplate (much less mention) neurostimulation in conjunction with a cardiac resynchronization and as noted above, Collins and Obel fail to contemplate improvement of cardiac performance by a combination of a cardiac resynchronization. Thus, the combination posed by the Examiner fails to reach the threshold of constituting a *prima facie* obviousness rejection and should be withdrawn.

Independent claim 17, as well as the claims dependent therefrom are neither taught nor suggested by Obel, Collins, and Limousin alone or in combination. Since the rejection based upon 35 USC § 103 has been overcome it should be withdrawn.

Claim 19 stands rejected under 35 USC § 103(a) as allegedly being unpatentable over Obel and Collins in view of the '187 patent to Adams (Adams).

Applicants note that the Examiner brings Adams forward and characterizes the reference as dealing with the treatment of relieving pain (and also apprehension and anxiety) and suggests that the claimed subject matter is not directed this subject matter. Indeed, claim 19 does not recite any of the foregoing but as set forth in claim 17 (from which claim 19 directly depends) the invention is directed to the following subject matter:

[a]n apparatus for treating a patient to improve cardiac performance and efficiency of the patient's heart, the apparatus comprising. (Emphasis added.)

Thus, the combination of references assembled by the Examiner fails to provide the claimed subject matter and does not constitute a *prima facie* rejection. Without meeting this necessary threshold Applicants are entitled to Letters Patent for the claimed subject matter.

In summary, Adams does not provide the teaching which is missing in Obel and Collins. Adams teaches the use of neuro stimulation to control pain during the time when a cardioversion/defibrillation shock is being delivered to a patient's heart. Adams is not concerned with a combination of nerve stimulation and CRT pacing therapies which together improve cardiac performance and efficiency of the patient's heart.

Applicants respectfully assert that the rejection of dependent claim 19 under 35 USC § 103(a) has been overcome. Accordingly, the rejection should be withdrawn.

III. Conclusion

Applicants respectfully suggest that all pending claims are in condition for allowance and the Examiner is earnestly solicited to issue a notice of allowance in due course.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: February 14, 2008

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